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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,261	09/10/2003	Adam L. Cohen	06530.0307	4026
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER LLOYD, EMILY M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,261	Applicant(s) COHEN ET AL.	
	Examiner Emily M. Lloyd	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 28-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/18/2003,1/29/2004,9/23/2004,3/17/2005,3/30/2005,5/16/2005.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I in the reply filed on 09 April 2007 is acknowledged.
2. Claims 28-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09 April 2007.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

4. The drawings are objected to because replacement sheets were received for Figures 1-9B but not Figures 10A-C. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several

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views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: most paragraphs on pages 3-6 of the specification are not numbered; the word "cavity" appears to be missing after the words "an open" on the 6th line from the bottom of page 5; the contents of [026] may refer to a different view and/or figure; [031] line 1 the word "of" should be added after the word "view" and the word "flusher" should be "flush"; [033] line 3 "related" should be "relates" or "is related"; [034] line 5 "when proximate tissue sites" should be revised for clarity; [040] line 6 "receiving" should say "receive"; [044] lines 2-5 should be revised for clarity and the reference to "port fitting 105 on the proximal end of the endoscope fitting 105" should be clarified; [048] line 11 the word "the" should be added after the word "between"; [059] line 8 the word "is" should be "are"; [069] line 6 the word "accordingly" shouldn't be capitalized or the line should be revised for clarity; and [077] line 6 the word "pull" should be "pulled".

Appropriate correction is required.

Claim Objections

6. Claim 25 is objected to because of the following informalities: it uses the elongated container to define itself. The Examiner suggests that the word "defines" be changed to "includes" (as used in claim 12) or "comprises". Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 14-20 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by International Publication Number WO 01/30242 (Paternuosto).

Regarding claim 14, Paternuosto discloses a device for storing a plurality of tissue samples comprising: an elongate container (container element 22 Figure 7) having a cavity (cavity 20 Figure 7) for storing a plurality of tissue samples, an open top (portion of container element 22 around hole 18 of half-shell 10B is open, Figure 7), and an open bottom (opening 24 at the bottom of container element 22 Figure 7) in flow communication with the open top (see Figure 7 and the 6th paragraph of page 4), wherein the open top and the open bottom are aligned with a longitudinal axis of the cavity (Figure 7); and a cutting portion (front rim 12 Figure 7) coupled to the open top and configured to cut the plurality of tissue samples that deposit in the cavity through the open top (5th paragraph of page 4); wherein a portion of the elongate container

adjacent the open bottom is configured to prevent the plurality of tissue samples from exiting the container via the open bottom (the portion of the container element 22 that surrounds the bottom opening 24 would function to keep the samples in the container).

Regarding claim 15, Paternuosto discloses the device of claim 14, wherein the cutting portion (front rim 12 Figures 5 and 7) selectively couples to the open top of the elongate container (Figure 7) and defines a through hole (hole 18 Figures 5 and 7) in flow communication with the open top, the cavity, and the open bottom (Figure 7).

Regarding claim 16, Paternuosto discloses the device of claim 14, wherein the cutting portion comprises an upper jaw (half-shell 10A Figure 6) and a lower jaw (half-shell 10B Figure 7) configured to cut tissue when the upper jaw mates with the lower jaw (last paragraph of page 5 and Figures 2 and 3).

Regarding claim 17, Paternuosto discloses the device of claim 16, wherein the lower jaw (half-shell 10B Figure 7) includes a through hole (hole 18 Figure 7), and wherein the lower jaw is coupled to the open top of the elongate container such that the through hole is in flow communication with the open top, the cavity, and the open bottom (adhesive 30 Figure 7 and the 4th paragraph of page 5).

Regarding claim 18, Paternuosto discloses the device of claim 16, wherein the upper jaw includes a protrusion (central portion 26 Figure 6) configured to push the plurality of tissue samples into the cavity (last paragraph of page 5).

Regarding claim 19, Paternuosto discloses the device of claim 18, wherein the protrusion extends adjacent an edge of the upper jaw (central portion 26 is adjacent to the edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claim 20, Paternuosto discloses the device of claim 16, wherein the upper jaw is configured to restrict the plurality of tissue samples from adhering to the upper jaw (central portion 26 Figure 6 and last paragraph of page 5).

Regarding claim 22, Paternuosto discloses the device of claim 16, wherein at least one of the upper jaw and the lower jaw has a support portion (support portion 16 Figure 2 and 3, see also the last paragraph of page 5) configured to allow the upper jaw and the lower jaw to rotate with respect to each other (last paragraph of page 3).

Regarding claim 23, Paternuosto discloses the device of claim 14, wherein the elongate container includes an angled base wall adjacent the open top (the wall of container element 22 adjacent base wall 14 is angled and adjacent the open top).

Regarding claim 24, Paternuosto discloses the device of claim 14, wherein the elongate container is configured to restrict the plurality of tissue samples from adhering to an inner wall of the elongated container (openings 24 Figure 7).

Regarding claim 25, Paternuosto discloses the device of claim 14, wherein the elongated container defines at least one hole in a side wall of the elongate container (openings 24 on the sides of container element 22, Figure 7).

Regarding claim 26, Paternuosto discloses the device of claim 14, wherein the portion of the elongate container adjacent the open bottom is hour-glass shaped (the walls of container element 22 immediately above and below hole 18 form an hour-glass shape, Figure 7).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-7, 9-13, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto.

Regarding claim 1, Paternuosto discloses a device for storing a plurality of tissue samples comprising: an elongate container (container element 22 Figure 7) having a cavity (cavity 20 Figure 7) for storing a plurality of tissue samples, an open top (portion of container element 22 around hole 18 of half-shell 10B is open, Figure 7), and an open bottom (opening 24 at the bottom of container element 22 Figure 7) in flow communication with the open top (see Figure 7 and the 6th paragraph of page 4); and a cutting portion (front rim 12 Figure 7) coupled to the open top and configured to cut the plurality of tissue samples that deposit in the cavity through the open top (5th paragraph of page 4). Paternuosto also discloses that a portion of the elongate container adjacent the open bottom is configured to prevent the plurality of tissue samples from exiting the container via the open bottom (the portion of the container element 22 that surrounds the bottom opening 24 would function to keep the samples in the container).

Paternuosto does not disclose that this configuration to prevent the plurality of tissue samples from exiting the container via the open bottom is by a restriction smaller than the open bottom. However, it would have been obvious to one of ordinary skill of the art at the time of the invention that such a change in shape could be made that would perform the same function as the invention of Paternuosto because this shape change would still allow the fluids to flow through the container (as described regarding openings 24 on the 6th paragraph of page 4) without losing the biopsy samples that the device is designed to cut and retain for testing (3rd through 5th paragraphs of page 2) and because such changes in shape are obvious (MPEP 2144.04 IV B).

Regarding claim 2, Paternuosto discloses the device of claim 1, wherein the cutting portion (front rim 12 Figures 5 and 7) selectively couples to the open top of the elongate container (Figure 7) and defines a through hole (hole 18 Figures 5 and 7) in flow communication with the open top, the cavity, and the open bottom (Figure 7).

Regarding claim 3, Paternuosto discloses the device of claim 1, wherein the cutting portion comprises an upper jaw (half-shell 10A Figure 6) and a lower jaw (half-shell 10B Figure 7) configured to cut tissue when the upper jaw mates with the lower jaw (last paragraph of page 5 and Figures 2 and 3).

Regarding claim 4, Paternuosto discloses the device of claim 3, wherein the lower jaw (half-shell 10B Figure 7) includes a through hole (hole 18 Figure 7) in flow communication with the open top and the open bottom, and wherein the lower jaw is coupled to the open top of the elongate container such that the through hole is in flow communication with the open top, the cavity, and the open bottom (adhesive 30 Figure 7 and the 4th paragraph of page 5).

Regarding claim 5, Paternuosto discloses the device of claim 3, wherein the upper jaw includes a protrusion (central portion 26 Figure 6) configured to push the plurality of tissue samples into the cavity (last paragraph of page 5).

Regarding claim 6, Paternuosto discloses the device of claim 5, wherein the protrusion extends around an edge of the upper jaw (central portion 26 is around the inner edge of the upper jaw via the peripheral portion 28, Figure 6).

Regarding claim 7, Paternuosto discloses the device of claim 3, wherein the upper jaw is configured to restrict the plurality of tissue samples from adhering to the upper jaw (central portion 26 Figure 6 and last paragraph of page 5).

Regarding claim 9, Paternuosto discloses the device of claim 3, wherein at least one of the upper jaw and the lower jaw has a support portion (support portion 16 Figure 2 and 3, see also the last paragraph of page 5) configured to allow the upper jaw and the lower jaw to rotate with respect to each other (last paragraph of page 3).

Regarding claim 10, Paternuosto discloses the device of claim 1, wherein the elongate container includes an angled base wall adjacent the open top (the wall of container element 22 adjacent base wall 14 is angled and adjacent the open top).

Regarding claim 11, Paternuosto discloses the device of claim 1, wherein the elongate container is configured to restrict the plurality of tissue samples from adhering to an inner wall of the elongated container (openings 24 Figure 7).

Regarding claim 12, Paternuosto discloses the device of claim 1, wherein the elongated container includes at least one hole on a side wall (openings 24 on the sides of container element 22, Figure 7).

Regarding claim 13, Paternuosto discloses the device of claim 1, wherein the portion of the elongate container adjacent the open bottom is hour-glass shaped (the walls of container element 22 immediately above and below hole 18 form an hour-glass shape, Figure 7).

Regarding claim 27, Paternuosto discloses the device of claim 14 (see the 102(b) rejection above). Paternuosto does not disclose that the configuration to prevent the

plurality of tissue samples from exiting the container via the open bottom is by a restriction in the portion of the elongate container adjacent the open bottom that is smaller than the open bottom. However, it would have been obvious to one of ordinary skill of the art at the time of the invention that such a change in shape could be made that would perform the same function as the invention of Paternuosto because this shape change would still allow the fluids to flow through the container (as described regarding openings 24 on the 6th paragraph of page 4) without losing the biopsy samples that the device is designed to cut and retain for testing (3rd through 5th paragraphs of page 2) and because such changes in shape are obvious (MPEP 2144.04 IV B).

13. Claims 8 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paternuosto in view of United States Patent 5662671 (Barbut et al.).

Regarding claims 8 and 21, Paternuosto discloses the devices of claims 3 and 16 in the 102(b) and 103(a) rejections above, respectively. Paternuosto does not disclose that the upper jaw defines a plurality of holes. Barbut et al. teaches the use of the upper jaw defining a plurality of holes (perforations 282 and 285 in clam shells 280 and 283, Figure 15A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such an upper jaw defining a plurality of holes as taught by Barbut et al. to provide for the movement of fluid and air while retaining the biopsy sample in the device in the invention of Paternuosto because this would provide an additional means of discharging air and liquids, which would better help the biopsy

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samples to move into the container element (Paternuosto 6th paragraph page 4) and permit blood flow out of the device (Barbut et al. Column 17 lines 45-48).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736


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